

MiniTube

Reprotoxicity in plastic materials – a boar semen case.

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Introduction

A large variety of plastic materials is used to make products for boar semen collection, processing, and insemination. The proper selection of raw materials and a suitable design of these products is necessary to provide hygienic and safe environments for boar semen. In particular, the plastics used in the manufacture of boar semen packaging units such as bottles, tubes, flat packs, or blisters, must meet the highest standards in order to protect and maintain the quality of the stored semen doses. In this context, the most fundamental prerequisite for any semen packaging unit is that it exerts no detrimental effect on the fertility of the stored semen. Exhaustive tests of the raw material to prove its neutrality with semen are therefore mandatory before manufacturing and commercializing the product.

Plastic materials used for semen packaging are polyolefins that offer great flexibility, mechanical strength, low weight, stability and high density. This group includes polyethylene (HDPE or LDPE), polypropylene (PP), polyvinylchloride (PVC), polyethylene terephthalate (PET), and other copolymers such as ethylene vinyl acetate (EVA).

Latent toxicity of multi-layer plastic films used to manufacture semen bags - a case study

Currently there are two widely varying production processes used to make boar semen packaging units. The most commonly used type of container is the boar semen tube or bottle made of pure polyethylene. The polyethylene is processed in a so-called blow-moulding machine, which melts plastic pellets and forms the semen tube or bottle from the hot and soft plastic material. No additives are needed for this straightforward production system.

Semen bags or blisters, however, are made from multi-layer plastic films which consist of 2 or more plastic layers which are glued together with an adhesive (Fig. 1). The plastic films contain plasticizers which provide the flexibility to the thin-walled bags or blisters; the most widely used plasticizers are phthalate esters.

These additives have long been suspected to have a negative effect on sperm cells and living organisms in general. The EU regulations classify phthalates as potentially teratogenic substances which can impair fertility (EC Regulation 1935/ 2004, EU Commission regulation 10/2011). The adhesives used to manufacture multi-layer plastic materials are not even regulated; however, it is obvious that their potential bio-toxicity (Felix et al. 2012, Isella et al. 2013) warrants as much examination and control as that used for the plasticizer.

Although it is long known that boar semen is extremely sensitive to any chemical impurity present in extenders due to deficient water or extender component quality, boar semen bags or blisters are still being manufactured with the above mentioned risky raw materials without having adequate quality control measures in place. Nerin et al. (2014) elucidated in their study the origin and reasons behind a dramatic reproductive failure in more than 40 Spanish sow herds in the spring of 2010. It is to their merit that we understand today that it is nearly impossible to produce a safe boar semen bag when plasticizers and adhesive are involved.

Nerin et al. went through a complete analysis of all the circumstances and parameters involved in the assisted reproduction procedures used with the sow herds. They found that the only common denominator was the use of semen doses packaged in semen bags of one source.

The chemical analyses of the used plastic bags revealed no less than 5 different toxic compounds:

- BADGE
- BADGE-H₂O
- BADGE-2H₂O
- Cyclic lactone
- Cyclic phthalates

BADGE is a derivative of Bisphenol A and long suspected to cause reproductive problems. The origin of these toxic compounds was found to be the adhesive used to manufacture the multi-layer plastic bags. It was also found that multi-layer plastic bags from the same batch could contain different amounts of adhesive and even different types of adhesive. This result explains why different concentrations of toxic compounds were found even in bags from the same batch.

Layer 2 - outer side, Layer 1 - inner side, Adhesive. www.minitube.de 7

The study also revealed that the toxic compounds of the plastic bags leach through intact plastic films into the extended semen and react there with the water molecules to form new compounds; namely BADGE-H₂O and BADGE-2H₂O. The total concentration of BADGE compounds and their derivatives detected by the chemical analyses conformed to the relevant European Regulation 10/2011/ EU for food safety, which allows a maximum value of 9 mg/kg food.

The effect on reproduction caused by toxic compounds which are in direct contact with sperm can therefore not be excluded although food toxicity levels are met. This difference can be explained by the mechanisms of toxic action.

Leaching processes depend on a variety of factors including contact time, temperature and initial concentration of the compounds in the plastic material. For this reason, the transport of toxic compounds will be higher in the semen doses stored for longer periods in plastic bags or in bags with a higher concentration of the leachable toxic compound.

Although the boar studs which used the defective semen bags performed rigorous quality control on the semen doses they produced, they could not detect any alteration in the semen parameters in their in vitro tests. Nerin could not even find any semen defects when her group performed in vitro penetration tests. Only in vivo fertility studies confirmed that the above mentioned compounds were indeed the main cause for the reproductive failure in the sows. The reprotoxicity did not affect conventional semen quality parameters, but it can be assumed from the presented data that it affected early embryonic development up to the blastocyst stage (d 6).

From the fertility data presented in Cristina Nerin's study, it is evident that the use of toxic semen bags resulted in an approximately 50 % loss of total born live piglets in the affected sow farms, which corresponds to a combined effect of pregnancy rates being reduced by more than 25 % and the litter size reduced by 2 piglets.

What we learned

Toxic compounds comprised in the multi-layer semen bags leach into the extended semen. Reliable quality control of the semen bags manufactured with plasticizers and adhesives is not possible because the concentration of toxic substances varies widely between the semen bags of the same batch.

There is no in vitro test with semen or embryos which could reliably indicate the toxicity of a bag because most of the reprotoxic effects unfold only after fertilization during the early embryonic development. Semen bags manufactured with plasticizers and adhesives can cause severe reprotoxicity at any time.

Boar semen tubes are safe

Boar semen tubes from Minitube are made from a pure polyethylene of pharma grade quality. Polyethylene is proven to contain neither plasticizers nor adhesives.

With comprehensive sperm safety test protocols applied to every raw material batch, Minitube assures that the fertility of boar semen packaged in its tubes will be not be impaired (Esch, 2014/2). Minitube's boar semen tubes are therefore marked with the SpermSafe label (Esch, 2014/1).

References:

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